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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,015	05/15/2002	Masayoshi Maki	56687(71526)	7186
21874	7590	12/29/2004	EXAMINER	
EDWARDS & ANGELL, LLP			FUBARA, BLESSING M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1615	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,015

Applicant(s)

MAKI ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, request for extension of time, amendment and remarks, all filed 11/29/04. Claims 6-11 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/29/04 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 6-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirano et al. (US 5,820,878).

Hirano discloses a percutaneous adhesive patch (abstract; column 2, line 12; column 3, lines 54, 62 and 63) and the adhesive patch comprises softening agents such as liquid paraffin, polybutene, castor oil, cottonseed oil, palm oil, coconut oil and process oil (column 2, lines 58-60). The patch further comprises additives such as tackifiers and the tackifiers that can be included in the patch preparation are saturated alicyclic hydrocarbon resins, rosin esters, alicyclic hydrocarbons, terpene hydrogenated resins and hydrogenated rosin esters (column 3, lines 22-

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29). The patch contains at least two hormones, estrogen and luteal hormones with estradiol as the preferred estrogen and luteal hormones selected from the group consisting of progesterone, hydroxyprogesterone caproate, medroxyprogesterone acetate, dydrogesterone, chlormadinone acetate, ethisterone, dimethisterone, norethisterone, norethisterone acetate, **norethisterone** enanthate, ethynodiol acetate, megestrol acetate and allylestrenol (column 2, lines 14-19).

Estrogen and the luteal hormones are present in amounts of 0.01 to 10% and with the luteal hormone present in about 1 to 5 times that of the estrogen (column 2, lines 20-29). Tackifier is present in amount of 0-40% by weight of the total amount of the preparation (column 3, lines 36-45) while the softening agent is present in amounts of 10-70% by weight of the total preparation (column 3, line 13). One of the essential ingredients of the patch is a polymer base that is styrene-butadiene-styrene block copolymer or styrene-isoprene-styrene block copolymer (column 2, lines 30-43) in amounts of 20 to 90% (column 3, line 5). The composition of Hirano may further contain polyisobutylene (Example 23) and although, estradiol in Example 23 is 0.50%, Example 23 is an exemplification of one of the embodiments since Hirano discloses that estradiol in the composition is in amounts of 0.1% to 10% (column 2, lines 20 and 21).

In example 13, the styrene-isoprene-styrene block copolymer is 287, the liquid paraffin, which is a softener is 41% and rosin ester tackifier is 25%. In examples 15 and 16, the amount of styrene-isoprene-styrene block copolymer is 20 and 29% respectively, amount of the liquid paraffin softener is 33 and 30% respectively and the tackifier is 36 and 20% respectively. While the amount of estradiol is disclosed in column 2, lines 20-26 to be from 0.01 to 10%, Examples 13, 15, 16 disclose the amounts of estradiol to be 1%, 1% and 0.5% and these amounts are not greater than or are not more than 2%..

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New claim 6 and 8 recite compositions that consist essentially of a base that contains..., the "contains" for the base opens up the base component to contain not just the styrene-isoprene-styrene copolymer but also other ingredients that may qualify as a base. Thus the presence of crotamiton is not excluded since the base contain.... Thus Hirano meets the limitation of the claims.

4. Claims 6-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hirano et al. (US 5,820,878).

The teachings in the disclosure of Hirano are discussed above. For the same reasons, Hirano meets the limitations of the claims under 35 USC 102(a).

Response to Arguments

5. Applicants' arguments filed 11/29/04 have been fully considered but they are not persuasive. Applicants state that the presence of crotamiton in the composition of Hirano removes Hirano as art since new claim 6 and 8 recite "consisting essentially of." However, as noted above, stating that the base "contains a styrene-isoprene-styrene block copolymer" opens up the base component of the composition to have or contain other ingredients and as such the base component does not exclude crotamiton.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al. (US 5,725,874).

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Oda discloses percutaneously absorbable preparations that comprise 20% styrene-isoprene-styrene block copolymer, polyisobutylene, liquid paraffin, rosin ester derivative, and 1% norethisterone (examples 44 and 45). The rosin ester derivative is 17% and 30% examples 44 and 45 respectively. Liquid paraffin, which is equivalent to the softener of instant claim 5 is 47% and 25% in examples 44 and 45 respectively. In examples 40 and 41, estradiol is the hormone active agent. Examples 40 and 41 disclose compositions containing estradiol and Example 44 discloses norethisterone containing composition and these Examples also contain polyisobutylene. 1% estradiol is not more than 2% estradiol.

Although Oda does not disclose a composition that contains both estradiol and norethisterone, Oda discloses individual compositions that contain estradiol and norethisterone. And "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the individual compositions that contain estradiol and norethisterone according to Oda. One having ordinary skill in the art would have been motivated to combine the two compositions in one composition with the expectation that the resultant composition that contains both estradiol and norethisterone would be effective for the same purpose as the individual compositions. *In re Kerkhoven*.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

